REMARKS

Reconsideration of this application is requested in view of the amendments to the claims and the remarks presented herein.

The claims in the application are claims 2 to 8 and 10 to 16, claims 1 and 9 are cancelled in this amendment.

All of the claims have been rejected under 35 USC 112, second paragraph, as being indefinite for the reasons set forth on pages 2 and 3 of the office action.

Applicants respectfully traverse these grounds of rejection since the amended claims are believed to properly define the invention. Claim 1 has been cancelled and replaced with new claim 15. Claim 9 has been rewritten to more clearly point out the invention and there is proper antecedent basis for the various terms in the dependent claims. The claims have also been amended to revise the terms objected to by the Examiner. Therefore, the claims are believed to comply with 35 USC 112 and withdrawal of this ground of rejection is requested.

All of the claims were rejected under 35 USC 103 as being obvious over the MDS Health Group reference. The Examiner states that the MDS reference discloses functional steps of sequential and conditional validation as shown in the flow chart of Figs. 2 and 5.

Any step in the flow chart in which a decision must be made reads as a step of conditional validation and all of the steps are sequential steps. Based on the collected data, a certification is issued at the last step illustrated by the results in Fig. 10. The Examiner states that MDS differs from claim 1 in that it does not disclose reinjecting cells which, according to the Examiner is well known in the art to perform dialysis treatment where blood cells are removed from the body and then reinjected. Therefore, it would be obvious to modify the process in this manner.

Applicants respectfully traverse this ground of rejection since the MDS reference would not render obvious Applicants' invention. The MDS reference discloses an electronic worksheet system for microbiology testing and reporting which comprises a work station coupled to a data base containing information relative to patients and a microbiology data base whereby the system provides with (i) assigning an identification number for accessing the databases and for associating with each tested sample with information relative to the concerned patient, (ii) collecting data relative to the test carried out on the sample by means of screen pages and (iii) with the delivering a report. MDS does not disclose, for each functional stage, a stage of sequential and conditional validation of said stage nor a condition of passage from a validation stage to another that would depend on results of processing data collected during this validation stage and a full completion of critical points by an operator on a screen page

associated with said functional stage.

With respect to pages 9 to 11 and Figure 2, MDS discloses functional stages that are not either punctually or systemically followed by a validation stage as recited in claim 1. In fact, the system disclosed in MDS is aimed at microbiology testing and reporting and not to quality management in a therapeutic process. Therefore, the MDS system does not require the same level of requirement in reliability and security as the process and system of Applicants' invention that finally results in a critical operation of cell reinjection into a patient.

Even assuming that "any step in the flow chart in which a decision must be made reads as a step of conditional validation". This assumption is not fulfilled in each functional stage of the MDS process illustrated in Figs. 2 and 5. On the contrary, among the 14 functional stages featured in Figure 2, only one stage 215 implies a decision (incubate specimen?) while among the 22 functional stages featured in Fig. 6, only 6 selecting stages (236, 238, 246, 248, 256 and 262) could be considered as implying a decision. In fact a selecting or decision stage cannot really be considered as a validation stage as recited in claim 15 because in the present invention, the condition of validation does not result from a decision formulated by an operator but indeed results from the processing of a series of actions completed by the said operator according to a standard operating procedure.

Moreover, it is important to note that the MDS system is intended to be used by a single operator while the quality management system of Applicants' invention is intrinsically aimed to be implemented by a plurality of operators along the entire collecting and therapeutic processes. Therefore, while the MDS teaches a worksheet system for microbiology testing and reporting, that does not include conditional validation stages systematically associated with each functional stage and including a full completion of critical points in a screen page associated with said functional stage, it would not have been obvious to for one skilled in the art to reach from the MDS teachings a process and system for quality management in therapeutic processes that require the highest level of security and reliability achieved by implementing sequential and conditional validation stages as recited in claim 15. Therefore, the MDS reference neither anticipates or renders obvious Applicants' invention and withdrawal of this ground of rejection is requested.

In view of the amendments to the claims and the above remarks, it is believed that the claims clearly point out Applicants' patentable contribution and favorable reconsideration of the application is requested.

Respectfully submitted,
Bierman, Muserlian and Lucas

By: _____
Charles A. Muserlian #19,683
Attorney for Applicants
Tel.# (212) 661-8000

CAM:ds
Enclosures

MARKED UP VERSION OF CLAIMS SHOWING CHANGES MADE

Claim 2 (twice amended) The process according to claim [1] 15, wherein validation of the final certification is conditional on [the] input of a validation password with a computer.

Claim 3 (twice amended) The process according to claim [1] 15, implemented in a data processing system, wherein with each validation step is associated at least one screen page

PO: [the] a screen page which provides the process operator

PEI: screen page corresponding to a stage of a process number

EP: title

EA: retrospective analysis screen page

EC: certification screen page

EI: anomalies screen page

which can be accessed on a display means of at least one computer workstation connected to said data processing system.

Claim 5 (twice amended) The process according to claim [1] 15 wherein [the] exit from certain stages (RA) of said process is conditional on printing the screen pages (EA) corresponding to these stages.

Claim 8 (twice amended) The process according to claim [1] 15 implemented in a preparation laboratory which deals with a control laboratory, wherein it further comprises stages for processing [the] results of control tests carried out on each batch of samples.

Claim 10 (twice amended) A system according to claim [9] 16, implemented in a preparation laboratory, [wherein it is further]

designed to execute management tasks of a preparation laboratory number n within this laboratory.

Claim 11 (twice amended) A system according to claim [9] 16, wherein it is connected to a communications network [in order] to exchange data with other entities selected from the group consisting of: treatment centers number n, cytapheresis services number n, collection centers number n and, bacteriological testing laboratories involved in a therapeutic process.

Claim 12 (twice amended) Application of the process and of [the] an information processing system used for quality management according to claim [1] 15 to cell therapy protocols.

Claim 13 (twice amended) Application of the process and of [the] an information processing system used for quality management according to claim [1] 15 to gene therapy protocols.

Claim 14 (twice amended) Application of the process and of [the] an quality management system according to claim [1] 15, allowing ongoing training of the operator and/or the monitoring of his or her level of knowledge.